

JUN - 2 2011

## 510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR§807.92(a).

### 807.92(a)(1)

#### Submitter Information

Esaote S.p.A.  
Via di caciolle 15  
50127 Firenze  
Italy

Contact Person: Allison Scott  
317.569.9500 x106  
ascott@ansongroup.com

Date: February 7, 2011

### 807.92(a)(2)

Trade Name: Model 7340 upgrade

Common Name: Ultrasound Imaging System

Classification Name(s):	Ultrasonic pulse Doppler imaging system	892.1550
	Ultrasonic pulsed echo imaging system	892.1560
	Diagnostic ultrasonic transducer	892.1570

Classification Number: 90IYN, 90IYO, 90ITX

### 807.92(a)(3)

#### Predicate Device(s)

k081794 and k091009	7340	Esaote, S.p.A.
k032875 and k033311	SD5500	Aloka
k003739 and k040719	4000	Aloka

807.92(a)(4)

**Device Description**

Model 7340 is a portable ultrasound system used to perform diagnostic general ultrasound studies. Its primary modes of operation are: B-Mode, M-Mode, Multi View (MView), Doppler, Color Flow Mapping (CFM), Amplitude Doppler (AD), Tissue Velocity Mapping (TVM) and Tissue Enhancement Imaging (TEI). The 7340 is equipped with a LCD Color Display. The full alphanumeric keyboard allows complete on-screen data entry of patient information and on-screen annotations. The 7340 can drive phased (PA), convex (CA), linear array (LA), Doppler probes and BiScan probes. The 7340 is equipped with an internal Hard Disk and with a DVD-RW disk drive that can be used for image storage. Data can also be stored directly to external archiving media (hard-disk, PC, server) via a LAN/USB port. Optional accessory devices available for the 7340 include an S-VHS video recorder; a monochrome or color page printer and a mobile trolley equipped with an insulation transformer. Model 7340 can be equipped with an internal battery that provides power when no main power is available.

The 7340 system has been cleared by FDA via k081794 and k091009.

Model 7340 upgrade, defined herein, combines the features of the Model 7340 with other, previously cleared software features and new software capabilities to assist a physician in making venous measurements. The venous imaging software package includes:

- 1) Dedicated Presets for Venous System Imaging, CFM and Doppler
- 2) QDP - Quality Doppler Profiles Technology based on Multigate Doppler algorithm
- 3) Optimized Probe management for Venous Intracranial Doppler

The 7340 system is manufactured under an ISO 9001:2000 and ISO 13485 certified quality system.

807.92(a)(5)

**Intended Use(s)**

Esaote's Model 7340 is a compact ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small Organs, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative (Abdominal), Laparoscopic and Other: Urologic. The 7340 system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculo-skeletal applications. The 7340 system provides imaging for venous system measurements.

807.92(a)(6)

**Technological Characteristics**

The 7340 model has been cleared via k081794 and k091009. The Aloka SD5500 system has been cleared via k032875 and k033311; the Aloka 4000 has been cleared via k003739 and k040719.

- Clinical uses for which the 7340 is designed are not changed by the 7340 upgrade, to be cleared via this submission.
- Clinical uses for which the Esaote 7340 and 7340 upgrade systems are designed are equivalent to those of the Aloka SD5500 ultrasound system, cleared via k032875 and k033311 and of the Aloks 4000 cleared via k k003739 and k040719.
- Esaote 7340 and 7340 upgrade, the Aloka SD5500 and Aloka 4000 ultrasound systems are able to provide the profile of the flow of the vessels under exam. The Aloka SD5500 system has been cleared via k032875 and k033311; the Aloka 4000 has been cleared via k003739 and k040719.
- Esaote 7340 and 7340 upgrade, Aloka SD5500 and Aloka 4000 ultrasound systems are designed to meet the IEC60601-1 and IEC60601-2-37 safety requirements.
- Esaote 7340 and 7340 upgrade, Aloka SD5500 and Aloka 4000 ultrasound systems provide an Acoustic Output Display feature per AIUM / NEMA standards, with equivalent Ispta and MI maximal values.

807.92(b)(1)

**Non-Clinical Testing**

Verification and validation tests have been conducted in accordance with design controls per CFR 820.30.

The system has been designed to meet the following standards:

- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-2-37
- ISO 10993-1
- AIUM/NEMA UD-3 – Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2 – Acoustic Output Measurement Standard for Diagnostic Ultrasound



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Esaote, S.p.A.  
% Mr. Mark Job  
Responsible Third Party Official  
Regulatory Technology Services LLC  
1394 25<sup>th</sup> Street NW  
BUFFALO MN 55313

JUN - 2 2011

Re: K110688  
Trade/Device Name: 7340 Ultrasound Systems  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulatory Class: II  
Product Code: IYN, IYO, and ITX  
Dated: May 17, 2011  
Received: May 18, 2011

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the 7340 Ultrasound Systems, as described in your premarket notification:

Transducer Model Number

<u>PA230</u>	<u>LA523</u>	<u>CA621</u>	<u>TRT33</u>
<u>PA240</u>	<u>LA532</u>	<u>CA631</u>	<u>TEE022</u>
<u>PA121</u>	<u>C5-2 R13</u>	<u>2 CW</u>	<u>TEE122</u>
<u>PA122</u>	<u>CA123</u>	<u>5CW</u>	<u>TEE132</u>
<u>PA023</u>	<u>CA421</u>	<u>HF CW</u>	<u>IOE323</u>
<u>LA332</u>	<u>CA1421</u>	<u>E8-5 R10P</u>	<u>LP323</u>
<u>LA424</u>	<u>CA430</u>	<u>EC123</u>	<u>BS230</u>
<u>LA435</u>	<u>CA431</u>	<u>EC1123</u>	<u>BC431</u>
<u>LA522</u>	<u>CA531</u>	<u>BE1123</u>	<u>BL433</u>

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Joshua Nipper at (301) 796-6524.

Sincerely Yours,

A handwritten signature in black ink, reading "Mary S. Pastel". The signature is fluid and cursive, with the first name "Mary" being the most prominent part.

Mary S. Pastel, Sc.D.  
Director  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure(s)

## Model 7340

### Indications for Use

---

510(k) Number (if known):

Device Name: 7340 Ultrasound Systems

Esaote's Model 7340 is a compact ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organ, Musculo-Skeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative (Abdominal), Laparoscopic and Other: Urologic. The 7340 system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculo-Skeletal applications. The 7340 system provides imaging for venous system flow profile.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

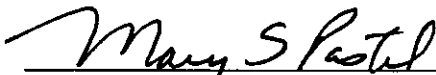
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
NEEDED)

---

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

  
Division Sign-off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K110608

## Mod.7340 upgrade

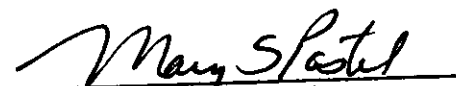
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping [TVM]	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 4, 5, 6, 7, 8, 9, 10, 13
Abdominal	P	P	P	P	P	P	P		P	P: 4, 5, 6, 7, 8, 9, 13
Intraoperative (Abdominal)	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9, 13
Intraoperative Neurological										
Pediatric	P	P	P	P	P	P	P		P	P: 4, 5, 6, 7, 8, 9, 13
Small Organ [1]	P	P	P		P	P	P		P	P: 4, 5, 6, 7, 8, 9, 13, 14
Neonatal Cephalic	P	P	P	P	P	P	P		P	P: 5, 6, 8, 9
Adult Cephalic	P	P	P	P	P	P	P		P	P: 6, 8, 9; N: 15
Cardiac [2]	P	P	P	P	P	P	P	P	P[16]	P: 4, 5, 6, 7, 8, 9, 11, 12
Transesophageal (Cardiac)	P	P	P	P	P	P	P	P	P	P: 4, 6, 9, 11, 12
Transesophageal (Non Cardiac)										
Transrectal	P	P	P		P	P	P		P	P: 4, 5, 6, 7, 8, 9, 13, 14
Transvaginal	P	P	P		P	P	P		P	P: 5, 6, 7, 8, 9, 14
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P	P	P	P	P		P	P: 4, 5, 6, 7, 8, 9, 10, 12, 13; N: 15
Laparoscopic	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9, 13
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P		P	P: 4, 5, 6, 7, 8, 9, 13, 14
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P		P	P: 4, 5, 6, 7, 8, 9, 13, 14
Other (Urological)	P	P	P		P	P	P		P	P: 4, 5, 6, 7, 8, 9, 13

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CW + CFM + PD
- [4] CMM
- [5] MView
- [6] 3D
- [7] 4D
- [8] VPan
- [9] XView
- [10] QIMT
- [11] Stress
- [12] Strain
- [13] TP View
- [14] ElaXto
- [15] Quality Doppler Profile (QDP)

[16] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

  
 (Division Sign-Off)  
 Division of Radiological Devices  
 Office of In Vitro Diagnostic Device Evaluation and Safety  
 510K K110688

Previously cleared via k081794 and k091009

Prescription Use Only Per 21 CFR 801 Part D  
Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - PA230

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	P	P	P	P	P	P	P		P	P: 6, 8, 9
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic	P	P	P	P	P	P	P		P	P: 6, 8, 9
Cardiac [2]	P	P	P	P	P	P	P	P	P[16]	P: 4, 6, 8, 9, 11, 12
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k091009

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CW + CFM + PD
- [4] CMM
- [6] 3D
- [8] VPan
- [9] XView
- [11] Stress
- [12] Strain

[16] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

*Mary S. Patel*  
 (Division Sign-Off)  
 Division of Radiological Devices  
 Office of In Vitro Diagnostic Device Evaluation and Safety  
 510K K110688

Prescription Use Only Per 21 CFR 801 Part D  
 Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - PA240

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	P	P	P	P	P	P	P		P	P: 8, 9
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic	P	P	P	P	P	P	P		P	P: 8, 9; N: 15
Cardiac [2]	P	P	P	P	P	P	P	P	P[16]	P: 4, 8, 9, 11, 12
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other [Urological]										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k091009

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CW + CFM + PD
- [4] CMM
- [8] VPan
- [9] XView
- [11] Stress
- [12] Strain
- [15] Quality Doppler Profile (QDP)

[16] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border



(Division Sign-Off)

Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety

510K

K110688

Prescription Use Only Per 21 CFR 801 Part D  
Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - PA121

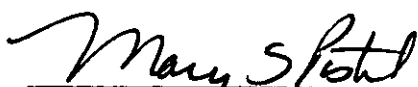
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	P	P	P	P	P	P	P		P	P: 8, 9
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	P	P	P	P	P	P	P		P	P: 4, 8, 9, 11, 12
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k091009

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CW + CFM + PD
- [4] CMM
- [8] VPan
- [9] XView
- [11] Stress
- [12] Strain

  
 (Division Sign-Off)  
 Division of Radiological Devices  
 Office of In Vitro Diagnostic Device Evaluation and Safety  
 510K K110688

Prescription Use Only Per 21 CFR 801 Part D  
 Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - PA122

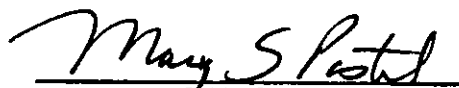
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P	P	P	P	P		P	P: 6, 8, 9
Small Organ [1]										
Neonatal Cephalic	P	P	P	P	P	P	P		P	P: 6, 8, 9
Adult Cephalic										
Cardiac [2]	P	P	P	P	P	P	P	P	P	P: 4, 6, 8, 9, 11, 12
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P	P	P	P	P		P	P: 6, 8, 9, 12
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k091009

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CW + CFM + PD
- [4] CMM
- [6] 3D
- [8] VPan
- [9] XView
- [11] Stress
- [12] Strain

  
 (Division Sign-Off)  
 Division of Radiological Devices  
 Office of In Vitro Diagnostic Device Evaluation and Safety  
 510K K110688

Prescription Use Only Per 21 CFR 801 Part D  
 Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - PA023


Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P	P	P	P	P			P: 8, 9
Small Organ [1]										
Neonatal Cephalic	P	P	P	P	P	P	P			P: 8, 9
Adult Cephalic										
Cardiac [2]	P	P	P	P	P	P	P			P: 4, 8, 9, 11, 12
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P	P	P	P	P			P: 8, 9
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k091009

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CW + CFM + PD
- [4] CMM
- [8] VPan
- [9] XView
- [11] Stress
- [12] Strain

  
 (Division Sign-Off)  
 Division of Radiological Devices  
 Office of In Vitro Diagnostic Device Evaluation and Safety  
 510K K110688

Prescription Use Only Per 21 CFR 801 Part D  
 Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

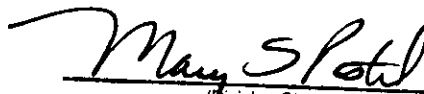
# 7340 - LA332

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9, 13
Small Organ [1]	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9, 13, 14
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9, 10, 12, 13; N: 15
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9, 13
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9, 13
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E  
Previously cleared via k091009

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CFM + PD
- [4] CMM
- [5] MView
- [6] 3D
- [8] VPan
- [9] XView
- [10] QIMT
- [12] Strain
- [13] TP View
- [14] ElaXto
- [15] Quality Doppler Profile (QDP)

  
(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
510K K110688

Prescription Use Only Per 21 CFR 801 Part D  
Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - LA424

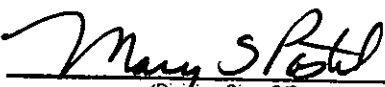
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P			P: 4, 5, 6, 8, 9, 13
Small Organ [1]	P	P	P		P	P	P			P: 4, 5, 6, 8, 9, 13
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P			P: 4, 5, 6, 8, 9, 12, 13
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P			P: 4, 5, 6, 8, 9, 13
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P			P: 4, 5, 6, 8, 9, 13
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k091009

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CW + CFM + PD
- [4] CMM
- [5] MView
- [6] 3D
- [8] VPan
- [9] XView
- [12] Strain
- [13] TP View

  
 (Division Sign-Off)  
 Division of Radiological Devices  
 Office of In Vitro Diagnostic Device Evaluation and Safety  
 510K K110688

Prescription Use Only Per 21 CFR 801 Part D  
 Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - LA435

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P			P: 4, 5, 6, 8, 9, 13
Small Organ [1]	P	P	P		P	P	P			P: 4, 5, 6, 8, 9, 13, 14
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P			P: 4, 5, 6, 8, 9, 12, 13
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P			P: 4, 5, 6, 8, 9, 13, 14
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P			P: 4, 5, 6, 8, 9, 13, 14
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k091009

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CW + CFM + PD
- [4] CMM
- [5] MView
- [6] 3D
- [8] VPan
- [9] XView
- [12] Strain
- [13] TP View
- [14] ElaXto

*Mary Speth*  
 (Division Sign-Off)  
 Division of Radiological Devices  
 Office of In Vitro Diagnostic Device Evaluation and Safety  
 510K K110688

Prescription Use Only Per 21 CFR 801 Part D  
 Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - LA522

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9, 13
Small Organ [1]	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9, 13, 14
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9, 10, 12, 13
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k091009

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CW + CFM + PD
- [4] CMM
- [5] MView
- [6] 3D
- [8] VPan
- [9] XView
- [10] QIMT
- [12] Strain
- [13] TP View
- [14] ElaXto

*May S Patel*  
 (Division Sign-Off)  
 Division of Radiological Devices  
 Office of In Vitro Diagnostic Device Evaluation and Safety  
 510K K110688

Prescription Use Only Per 21 CFR 801 Part D  
 Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - LA523

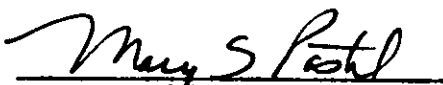
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9, 13
Small Organ [1]	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9, 13, 14
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9, 10, 12, 13, N:15
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9, 13, 14
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9, 13, 14
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k091009

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CFM + PD
- [4] CMM
- [5] MView
- [6] 3D
- [8] VPan
- [9] XView
- [10] QIMT
- [13] TP View
- [14] ElaXto
- [15] Quality Doppler Profile (QDP)

  
 (Division Sign-Off)  
 Division of Radiological Devices  
 Office of In Vitro Diagnostic Device Evaluation and Safety  
 510K K110688

Prescription Use Only Per 21 CFR 801 Part D  
 Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - LA532

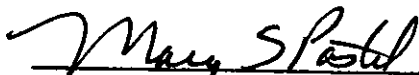
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9, 13
Small Organ [1]	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9, 13
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9, 12, 13
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k091009

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CW + CFM + PD
- [4] CMM
- [5] MView
- [6] 3D
- [8] VPan
- [9] XView
- [12] Strain
- [13] TP View

  
 (Division Sign-Off)  
 Division of Radiological Devices  
 Office of In Vitro Diagnostic Device Evaluation and Safety  
 510K K110688

Prescription Use Only Per 21 CFR 801 Part D  
 Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - C5-2 R13

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 8, 9, 10
Abdominal	P	P	P		P	P	P		P	P: 5, 6, 8, 9
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5, 6, 8, 9
Small Organ [1]										
Neonatal Cephalic	P	P	P		P	P	P		P	P: 5, 6, 8, 9
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 6, 8, 9, 12
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k091009

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CFM + PD
- [5] MView
- [6] 3D
- [8] VPan
- [9] XView
- [12] Strain

*Mary S. Patel*  
 (Division Sign-Off)  
 Division of Radiological Devices  
 Office of In Vitro Diagnostic Device Evaluation and Safety  
 510K K110688

Prescription Use Only Per 21 CFR 801 Part D  
 Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - CA123

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5, 6, 8, 9
Small Organ [1]	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9
Neonatal Cephalic	P	P	P		P	P	P		P	P: 5, 6, 8, 9
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9, 11, 12
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 6, 8, 9, 12; N: 15
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k091009

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CFM + PD
- [4] CMM
- [5] MView
- [6] 3D
- [8] VPan
- [9] XView
- [11] Stress
- [12] Strain
- [15] Quality Doppler Profile (QDP)

*Mary S. Pott*  
 (Division Sign-Off)  
 Division of Radiological Devices  
 Office of In Vitro Diagnostic Device Evaluation and Safety  
 510K K110688

Prescription Use Only Per 21 CFR 801 Part D  
 Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - CA421

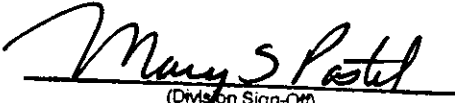
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 8, 9, 10
Abdominal	P	P	P		P	P	P		P	P: 5, 6, 8, 9
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5, 6, 8, 9
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 6, 8, 9, 12
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 8, 9

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k091009

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CFM + PD
- [5] MView
- [6] 3D
- [8] VPan
- [9] XView
- [10] QIMT
- [12] Strain

  
 (Division Sign-Off)  
 Division of Radiological Devices  
 Office of In Vitro Diagnostic Device Evaluation and Safety  
 510K K110688

Prescription Use Only Per 21 CFR 801 Part D  
 Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - CA1421

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 8, 9, 10
Abdominal	P	P	P		P	P	P		P	P: 5, 6, 8, 9
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5, 6, 8, 9
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 6, 8, 9, 12
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 8, 9

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k091009

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CFM + PD
- [5] MView
- [6] 3D
- [8] VPan
- [9] XView
- [10] QIMT
- [12] Strain

*Mary Speth*  
 (Division Sign-Off)  
 Division of Radiological Devices  
 Office of In Vitro Diagnostic Device Evaluation and Safety  
 510K 1510688

Prescription Use Only Per 21 CFR 801 Part D  
 Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - CA430


Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 8, 9, 10
Abdominal	P	P	P		P	P	P		P	P: 5, 6, 8, 9
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 6, 8, 9
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 8, 9

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k091009

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CFM + PD
- [5] MView
- [6] 3D
- [8] VPan
- [9] XView
- [10] QIMT
- [12] Strain

  
 (Division Sign-Off)  
 Division of Radiological Devices  
 Office of In Vitro Diagnostic Device Evaluation and Safety  
 510K K110688

Prescription Use Only Per 21 CFR 801 Part D  
 Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - CA431

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 8, 9, 10
Abdominal	P	P	P		P	P	P		P	P: 5, 6, 8, 9
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5, 6, 8, 9
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 6, 8, 9, 12
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P		P	P: 5, 6, 8, 9
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P		P	P: 5, 6, 8, 9
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 8, 9

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k091009

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CFM + PD
- [5] MView
- [6] 3D
- [8] VPan
- [9] XView
- [10] QIMT
- [12] Strain

*Mary S. Patel*  
 (Division Sign-Off)  
 Division of Radiological Devices  
 Office of In Vitro Diagnostic Device Evaluation and Safety  
 510K K110688

Prescription Use Only Per 21 CFR 801 Part D  
 Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - CA531

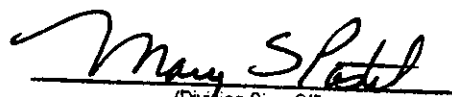
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 8, 9, 10
Abdominal	P	P	P		P	P	P		P	P: 5, 6, 8, 9
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	5, 6, 8, 9
Small Organ [1]	P	P	P		P	P	P		P	
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 6, 8, 9, 12
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 8, 9

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k091009

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CFM + PD
- [4] CMM
- [5] MView
- [6] 3D
- [8] VPan
- [9] XView
- [10] QIMT
- [12] Strain

  
 (Division Sign-Off)  
 Division of Radiological Devices  
 Office of In Vitro Diagnostic Device Evaluation and Safety  
 510K 14110688

Prescription Use Only Per 21 CFR 801 Part D  
 Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - CA621


Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 8, 9, 10
Abdominal	P	P	P		P	P	P		P	P: 5, 6, 8, 9
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5, 6, 8, 9, 10
Small Organ [1]										P: 5, 6, 8, 9
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 6, 8, 9, 12
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 8, 9

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k091009

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CFM + PD
- [5] MView
- [6] 3D
- [8] VPan
- [9] XView
- [10] QIMT
- [12] Strain

  
(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110688

Prescription Use Only Per 21 CFR 801 Part D  
Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - CA631

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 8, 9, 10
Abdominal	P	P	P		P	P	P		P	P: 5, 6, 8, 9
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5, 6, 8, 9
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 6, 8, 9, 12
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 8, 9

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k091009

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Combined modes are: B + M + PW + CFM + PD

[4] CMM

[5] MView

[6] 3D

[8] VPan

[9] XView

[10] QIMT

[12] Strain

*May S Patel*  
(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
510K K110688

Prescription Use Only Per 21 CFR 801 Part D  
Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - 2 CW

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]				P						
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E  
Previously cleared via k091009

[1] Small Organs includes Breast, Thyroid and Testicles  
[2] Cardiac is Adult and Pediatric

*Mary Speth*  
(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
510K K110688

Prescription Use Only Per 21 CFR 801 Part D  
Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

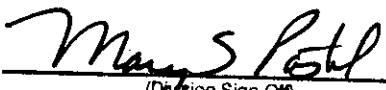
# 7340 - 5 CW

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				P						
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E  
Previously cleared via k091009

[1] Small Organs includes Breast, Thyroid and Testicles  
[2] Cardiac is Adult and Pediatric

  
(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
510K K110688

Prescription Use Only Per 21 CFR 801 Part D  
Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - HF CW

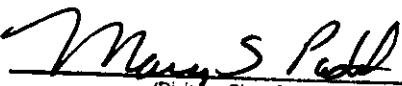
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				P						
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k103152

- [1] Small Organs includes Breast, Thyroid and Testicles  
 [2] Cardiac is Adult and Pediatric

  
 (Division Sign-Off)  
 Division of Radiological Devices  
 Office of In Vitro Diagnostic Device Evaluation and Safety  
 510K K110688

Prescription Use Only Per 21 CFR 801 Part D  
 Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - E8-5 R10P

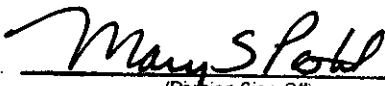
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	P	P	P		P	P	P		P	P: 5, 6, 8, 9
Transvaginal	P	P	P		P	P	P		P	P: 5, 6, 8, 9
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 8, 9

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k091009

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CFM + PD
- [5] MView
- [6] 3D
- [8] VPan
- [9] XView

  
 (Division Sign-Off)  
 Division of Radiological Devices  
 Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110688

Prescription Use Only Per 21 CFR 801 Part D  
 Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - EC123

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	P	P	P		P	P	P		P	P: 5, 6, 8, 9
Transvaginal	P	P	P		P	P	P		P	P: 5, 6, 8, 9
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 8, 9

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k091009

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CFM + PD
- [5] MView
- [6] 3D
- [8] VPan
- [9] XView

*Mary S Patel*  
 (Division Sign-Off)  
 Division of Radiological Devices  
 Office of In Vitro Diagnostic Device Evaluation and Safety  
 510K K110688

Prescription Use Only Per 21 CFR 801 Part D  
 Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - EC1123

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 8, 9, 10
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	P	P	P		P	P	P		P	P: 5, 6, 8, 9
Transvaginal	P	P	P		P	P	P		P	P: 5, 6, 8, 9
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 8, 9

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k091009

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CFM + PD
- [5] MView
- [6] 3D
- [8] VPan
- [9] XView
- [10] QIMT
- [14] ElaXto

*May S Patel*  
 (Division Sign-Off)  
 Division of Radiological Devices  
 Office of In Vitro Diagnostic Device Evaluation and Safety  
 510K K110688

Prescription Use Only Per 21 CFR 801 Part D  
 Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - BE1123

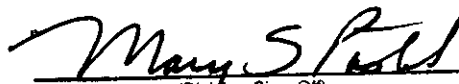
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 7, 8, 9
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	P	P	P		P	P	P		P	P: 5, 6, 7, 8, 9
Transvaginal	P	P	P		P	P	P		P	P: 5, 6, 7, 8, 9
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)	P	P	P		P	P	P		P	P: 5, 6, 7, 8, 9

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k091009

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CFM + PD
- [5] MView
- [6] 3D
- [7] 4D
- [8] VPan
- [9] XView

  
 (Division Sign-Off)  
 Division of Radiological Devices  
 Office of In Vitro Diagnostic Device Evaluation and Safety  
 510K K110688

Prescription Use Only Per 21 CFR 801 Part D  
 Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

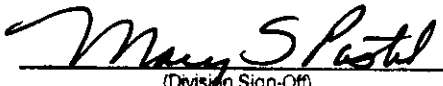
# 7340 - TRT33

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9, 13, 14
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9, 13

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E  
Previously cleared via k091009

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CFM + PD
- [4] CMM
- [5] MView
- [6] 3D
- [8] VPan
- [9] XView
- [13] TP View
- [14] ElaXto

  
(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
510K K110688

Prescription Use Only Per 21 CFR 801 Part D  
Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - TEE022

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)	P	P	P	P	P	P	P	P	P	P: 4, 6, 9, 11, 12
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k091009

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CW + CFM + PD
- [4] CMM
- [6] 3D
- [9] XView
- [11] Stress
- [12] Strain

*Mary Spall*  
 (Division Sign-Off)  
 Division of Radiological Devices  
 Office of In Vitro Diagnostic Device Evaluation and Safety  
 510K K110688

Prescription Use Only Per 21 CFR 801 Part D  
 Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - TEE122

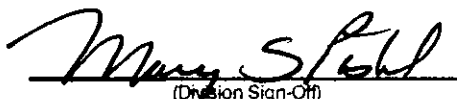
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)	P	P	P	P	P	P	P	P	P	P: 4, 6, 9, 11, 12
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k091009

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CW + CFM + PD
- [4] CMM
- [6] 3D
- [9] XView
- [11] Stress
- [12] Strain

  
 (Division Sign-Off)  
 Division of Radiological Devices  
 Office of In Vitro Diagnostic Device Evaluation and Safety  
 510K K110688

Prescription Use Only Per 21 CFR 801 Part D  
 Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - TEE132


Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)	P	P	P	P	P	P	P	P	P	P: 4, 6, 9, 11, 12
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k091009

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CW + CFM + PD
- [4] CMM
- [9] XView
- [11] Stress
- [12] Strain

  
 (Division Sign-Off)  
 Division of Radiological Devices  
 Office of In Vitro Diagnostic Device Evaluation and Safety  
 510K K110688

Prescription Use Only Per 21 CFR 801 Part D  
 Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - IOE323


Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9, 13
Intraoperative (Abdominal)	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9, 13
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9, 13
Small Organ [1]	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9, 13
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9, 12, 13
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9, 13
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9, 13
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k091009

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CFM + PD
- [4] CMM
- [5] MView
- [6] 3D
- [8] VPan
- [9] XView
- [12] Strain
- [13] TP View

  
 (Division Sign-Off)  
 Division of Radiological Devices  
 Office of In Vitro Diagnostic Device Evaluation and Safety  
 510K K110688

Prescription Use Only Per 21 CFR 801 Part D  
 Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - LP323

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9, 13
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic	P	P	P		P	P	P		P	P: 4, 5, 6, 8, 9, 13
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k091009

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CFM + PD
- [4] CMM
- [5] MView
- [6] 3D
- [8] VPan
- [9] XView
- [13] TP View

*Mary Spital*  
 (Division Sign-Off)  
 Division of Radiological Devices  
 Office of In Vitro Diagnostic Device Evaluation and Safety  
 510K K110688

Prescription Use Only Per 21 CFR 801 Part D  
 Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - BS230

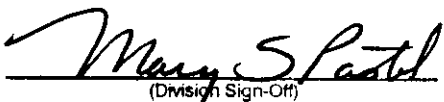
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	P	P	P	P	P	P	P	P	P	P: 4, 6, 7, 8, 9, 11, 12
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k091009

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CW + CFM + PD
- [4] CMM
- [6] 3D
- [7] 4D
- [8] VPan
- [9] XView
- [11] Stress
- [12] Strain

  
(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety

510K 15110688

Prescription Use Only Per 21 CFR 801 Part D  
Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - BC431

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6, 7, 8, 9, 10
Abdominal	P	P	P		P	P	P		P	P: 5, 6, 7, 8, 9
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5, 6, 7, 8, 9, 12
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k091009

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CFM + PD
- [5] MView
- [6] 3D
- [7] 4D
- [8] VPan
- [9] XView
- [12] Strain

*Mary S. Patel*  
 (Division Sign-Off)  
 Division of Radiological Devices  
 Office of In Vitro Diagnostic Device Evaluation and Safety  
 510K B110688

Prescription Use Only Per 21 CFR 801 Part D  
 Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

# 7340 - BL433

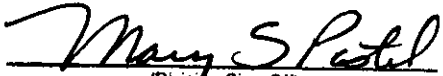
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 4, 5, 6, 7, 8, 9, 13
Small Organ [1]	P	P	P		P	P	P		P	P: 4, 5, 6, 7, 8, 9, 13
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 4, 5, 6, 7, 8, 9, 13
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P		P	P: 4, 5, 6, 7, 8, 9, 13
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P		P	P: 4, 5, 6, 7, 8, 9, 13
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k091009

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CFM + PD
- [4] CMM
- [5] MView
- [6] 3D
- [7] 4D
- [8] VPan
- [9] XView
- [13] TP View

  
 (Division Sign-Off)  
 Division of Radiological Devices  
 Office of In Vitro Diagnostic Device Evaluation and Safety

510K B110688

Prescription Use Only Per 21 CFR 801 Part D  
 Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)